NIH POLICY MANUAL

6380-3 - SALE OF RESEARCH SUBSTANCES AND LIVING ORGANISMS PRODUCED OR ACQUIRED UNDER R&D CONTRACTS

Issuing Office: OA/OCM/DAPE 301-496-6014
Release Date: 08/15/97

1. **Explanation of Material Transmitted:** The purpose of this Manual Chapter is to identify issues to be considered by the NIH contracting activities in awarding, administering, and closing contracts involving production or acquisition of research substances and living organisms and their sale to researchers and others engaged in biomedical and behavioral research.

2. **Filing Instructions:**

   Remove: None - Replace I&I Memorandum DCG 87-2 (Rev. 1) Sale of Research Substances and Living Organisms Produced or Acquired Under R&D Contracts.

   Insert: NIH Manual 6380-3, Sale of Research Substances and Living Organisms Produced or Acquired Under R&D Contracts, dated 08/15/97.

3. **Distribution:** NIH Manual Mailing Keys F-401, F-404, and F-407.

PLEASE NOTE: For information on:

- content of this chapter, contact the Division of Acquisition Policy and Evaluation, OCM, OA, on (301) 496-6014.
- NIH Manual Mailing Keys, contact the Division of Support Services, ORS, on (301) 496-4808.
- NIH Manual System, contact the Division of Management Support, OMA, on (301) 496-2832.
- on-line information, use: http://www3.od.nih.gov/oma/manualchapters/

A. Purpose:

The purpose of this Manual Chapter is to identify issues to be considered by the NIH contracting activities in awarding, administering, and closing contracts involving production or acquisition of research substances and living organisms and their sale to

researchers and others engaged in biomedical and behavioral research.

B. Background:

1. Legislation concerning public health gives the Secretary, HHS, broad authority to make "substances and living organisms" available to researchers and other users. Such research substances and living organisms may be purchased and sold by the Government itself, or the Government may arrange the sale and distribution of such research substances and living organisms by a contractor who will produce or acquire them.

2. By memorandum dated March 2, 1981, subject: Sale of Research Materials (Appendix 1), Office of General Counsel (OGC), provided guidance governing the use of contracts for the production and sale of research substances and living organisms. The OGC advised, based on a property statute (40 U.S.C. 485), that if the Government receives the proceeds generated by the sale directly, whether the sale is conducted by the Government or the contractor, the proceeds must be paid into the Treasury as miscellaneous receipts. But where the Government receives the proceeds from the sale indirectly, as where the contractor would produce the research substances and/or living organisms, sell them to third parties and bill the Government for reimbursement in a net amount (representing actual cost of producing research substances and living organisms less proceeds from the sale), these proceeds need not be paid into the Treasury and may be used by the agency as offset against costs incurred under the contract.

C. Procedures:

The following basic principles of contracts with revenue-generating features pertain to any contract involving generation of income from the sale of research substances and living organisms:

1. A contract cannot be formulated solely for the purpose of distributing income-generating research substances and living organisms. The research substances and/or living organisms to be distributed must be in excess to the needs of the contractor in its full performance of the contract (e.g., the contractor should be using some of the research substances and/or living organisms or developing them or improving them, etc.).

   The revenues generated by sales must not offset the total costs incurred under the contract. In accordance with OGC, a self-sustaining contract is not admissible.

2. The HHS authority for sale of research substances and living organisms applies even when they are commercially available and HHS establishes prices, which may differ from the commercial marketplace.

   Such an HHS enterprise is not considered unfair competition by the

Government (i.e., in violation of Competition in Contracting Act) or an unwarranted interference in the commercial marketplace.

3. The contract shall identify the research substances and living organisms to be produced and made available to potential recipients and shall include an estimate of the quantities to be distributed. The contract should specify any exclusions and/or restrictions to distribution, the prices to be charged, and any eligibility requirements of potential recipients.

   The prices to be charged may not exceed the cost of the research substances and living organisms, including handling and shipping costs. Price differentials may be placed on the charges to the requestors of the materials (e.g., lesser cost to non-profit than profit organizations).

   The contracting officer may direct the contractor to make gratis shipments when this is determined to be scientifically desirable by the project officer.

   Any changes in quantities of items to be produced and distributed are subject to bilateral agreement between the contracting parties. Prices to be charged for research substances and living organisms are to be established unilaterally by the NIH.

4. The contract shall describe any relevant standards for the safety and use of such research substances and living organisms. This information must also be furnished to eventual buyers or recipients. Where appropriate, users shall also be required to execute an assurance certificate whereby they agree not to use the research substances and living organisms in any unauthorized or unsafe way. Such assurances shall be retained as part of the contract records.

5. An assessment of the nature of the research substances and living organisms produced and its distribution would determine whether the contract should include a release and indemnity agreement. If the project officer determines that there is potential risk, language similar to that stated below may be incorporated in the resultant contract after consultation with the OGC:

"The recipients of the (specify material) agree to indemnify and hold harmless the United States,

(name of contractor)

and

(contributor of any material if applicable),

from any claims, costs, damages, or expenses resulting from any injury (including death), damage or loss that may arise from the use of the (material) ."

6. The contract shall contain billing instructions and detailed procedures for maintaining accounting records:

   a. Whenever possible, recipients shall be billed directly for research substances and living organisms plus shipping costs on a prepaid or COD basis in order to facilitate bookkeeping on sales and avoid extensive follow-up of delinquent payments.

   b. The contractor shall keep an accurate account of all sales and proceeds so that the contract estimated cost may be adjusted, as necessary, in accordance with the Limitation of Cost (or Funds) Clause.

   c. The contractor shall invoice the Government for reimbursable costs under the contract no less frequently than monthly. All revenues received in the billing period shall be used to offset costs of performance. Thus, the actual collection for monies received from recipients for research substances and living organisms and shipping will be offset against the gross billing, leaving a net amount due on the invoice.

   d. The contract shall specify that should the amount of revenues generated by the sale of research substances and living organisms exceed the total costs of performance plus-fixed-fee, the excess shall be refunded to DHHS, NIH, in accordance with the contracting officer's instructions for transmittal to the United States Treasury. Specific procedures to be followed by the contractor for refund of contract revenues received after submission of a completion voucher should be stated in the contract close-out letter. A statement can be made as follows:

   "If revenues are received after submission of the completion voucher, you shall forward a check to the NIH in the amount of the revenues received. Such check shall be made out to Department of Health and Human Services, NIH, and sent to (use address stated in Section G of the contract, Article, entitled "Invoice Submission")."

7. The contractor shall, under the reporting requirements of the contract, submit a Monthly Summary of Sales, which identifies recipients, item description, quantities, unit cost, etc. The monthly report shall also serve as a notification to the project officer/contracting officer of recipients who are delinquent in making payments on research substances and living organisms delivered by the contractor. The project office will make a scientific determination and advise the contracting officer whether it is in the Government's best interests for the contractor to continue to make deliveries to users who are delinquent in making payments.

8. Fee under the contract, if any, shall be computed and negotiated using the

weighted guidelines basis on the total estimated cost of the contract, not on the basis of anticipated net total cost to the Government after sales of research materials. Contractor risk and management contribution and all other factors underlying the award of appropriate fee levels are not impacted in any way by the cost-offset features of the contract.

9. Although legal authority does not preclude use of firm-fixed-price-type contracts in revenue generating situations, they do not appear to be an appropriate contract type for such situations.

   The need for close monitoring of revenues generated by the sale of research substances and living organisms under the contract, and the concomitant offset against the cost of contract performance, requires the assurance that the contractor's accounting system be adequate. In accordance with FAR l6.l04, the contracting officer shall have ensured that this is the case prior to entering into a cost-reimbursement contract. Such assurance is not required in a firm-fixed-price environment, which could lead to a situation where the accounting system is inadequate for separating direct contract costs from generated revenues, a necessity in the implementation of contracts involving sale of research substances and/or living organisms.

D. Records Retention and Disposal:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1 - "Keeping and Destroying Records," NIH Records Control Schedule, Item 2600-A-4, Routine Procurement Files. Refer to the NIH Manual Chapter for specific disposition instructions.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. Pursuant to General Records Schedule 20, Item 14 - Electronic Mail Records, e-mail messages which meet this definition should be copied to a recordkeeping system--either hard copy or electronic--and then deleted from the e-mail system.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages.

E-mail messages must also be provided to members of Congress or Congressional committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are sometimes retained for significatn periods of time, e-mail messages and attachments may be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

Please see paper copy for the following Appendix information:

Appendix 1 - OGC Memo dated March 2, 1981

Appendix 2 - Sample Clauses